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10/699,521	10/31/2003	Guohua Chen	ALZA-0129	4222

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,521	CHEN ET AL.	
	Examiner	Art Unit	
	ERIC E. SILVERMAN	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-122* is/are pending in the application.

4a) Of the above claim(s) *14-17,21-54-56,and 73-121* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18-20,22-53,57-73, and 122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed 10/14/2008 has been received.

Election/Restrictions

Applicants' argue that claim 17 was improperly withdrawn, and should be rejoined. In response, in the submission filed 1/22/2007, applicants listed the claims that read on the elected species; claim 17 was not included in that listing. Claim 17 was withdrawn based on applicants' submission. See page 3, first fill paragraph, final sentence of the 1/22/07 response. Applicants' traverse of the election of species requirement as applied to claim 17 is not timely, because the first response to the requirement did not traverse the election of species. See response filed 4/22/2007 and Office action mailed 4/9/2008 at 2. Claim 17 remains withdrawn.

Claims 1-122 are pending; claims 14-17, 21, 54- 56, 73-121 are withdrawn; claims 1-13, 18-20, 22-53, 57-73, and 122 are treated on the merits in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 18-20, 22-24, 28-39, and 122 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection is maintained for reasons of record. In addition, the new recitation of "reduced initial burst" is indefinite. The term "reduced" is comparative. The claim does not specify what the initial burst is compared to in order to determine whether it is

"reduced". As such, the artisan has no way to know whether a composition according to the claim has a "reduced" initial burst, as claimed.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants' argue that the term "low molecular weight" is defined in paragraph [0059] of the specification. The definition in that paragraph is itself indefinite. The definition in paragraph 59 provides a range within a range, which is unclear because it is uncertain whether the broader or narrower range embodies the claim. Further, the molecular weights in paragraph 59 lack units. Molecular weight may be measured in different units, such as daltons, g/mol, or kilodaltons. Finally, the molecular weights in paragraph 59 are determined by gel permeation chromatography. Gel permeation chromatography determines the molecular weight of an analyte by directly comparison of the analyte to polymer standards with known molecular weights. The results of a gel permeation chromatography analysis will differ depending on what standard is used; for example, comparison to a polystyrene standard will give different results that comparison to a polymethylmethacrylate standard. Because the alleged definition of low molecular weight in the specification is indefinite, this definition cannot be relied on to make the term "low molecular weight" in the claims definite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-12, 18-20, 22, 24, 29-35, 40-52, 57-65, 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,130,200 Brodbeck in view of US 5,760,077 to Shahnian.

The teachings of Brodbeck were discussed in the previous Office Action. Also note that Brodbeck teaches the use of particles of active agent, with particle sizes from 0.1-100 microns, or from 1-25 microns. Col. 21.

What is lacking from Brodbeck is a teaching of one or more of the anesthetics of claim 1.

Shahinian teaches tetracaine, an analgesic of claim 1, was known prior to the invention to have anesthetic properties and to be useful for long-term (sustained release) administration. Col. 3, lines 65-47.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include tatracaine in the invention of Brodbeck. This modification involves no more than adding a recognized anesthetic of Shahimian to a composition that already has an anesthetic (Brodbeck). Combination of elements recognized in the prior art as having the same purpose in order to achieve the recognized purpose is prime facie obvious. Here, the combination represents no more than combining known anesthetis in order to achieve a composition that provides anesthesia. It follows that the claims constitute obvious subject matter.

Claims 1-8, 10-13, 18-20, 22-39, 40-53, 57-72 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,130,200 Brodbeck in view of US 6,432,415 to Osborne and US 5,760,077 to Shahinian.

The of Brodbeck and Osborne were discussed in the previous Office Action.

What is lacking from Brodbeck and Osborne is a teaching of one or more of the anesthetics of claim 1.

Shahinian teaches tetracaine, an analgesic of claim 1, was known prior to the invention to have anesthetic properties and to be useful for long-term (sustained release) administration. Col. 3, lines 65-47.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include tatracaine in the invention of Brodbeck. This modification involves no more than adding a recognized anesthetic of Shahimian to a composition that already has an anesthetic (Brodbeck). Combination of elements recognized in the prior art as having the same purpose in order to achieve the recognized purpose is prime facie obvious. Here, the combination represents no more than combining known anesthetis in order to achieve a composition that provides anesthesia. Further, Osborne directly suggests the use of anesthetics, so adding a known anesthetic is merely following the express suggestion of the prior art.

Claims 1-12, 18-20, 22, 24, 29-35, 40-52, 57-65, 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,130,200 Brodbeck in view of US 5,614,206 to Randolph.

Brodbeck was discussed in the previous Office Action.

What is lacking is a teaching of the anesthetics of instant claims, such as bipivacaine.

Randolph teaches that bipivacaine is an anesthetic suitable for formulation in a sustained release composition. Claims 12, 20, and 26.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include tatracaine in the invention of Brodbeck. This modification involves no more than adding a recognized anesthetic of Randolg to a composition that already has an anesthetic (Brodbeck). Combination of elements recognized in the prior art as having the same purpose in order to achieve the recognized purpose is prime facie obvious. Here, the combination represents no more than combining known anesthetis in order to achieve a composition that provides anesthesia. It follows that the claims constitute obvious subject matter.

Claims 1-13, 18-20, 22-53, 57-72, and 122are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,130,200 Brodbeck in view of US 6,432,415 to Osborne and US 5,614,206 to Randolph.

The teachings of Brodbeck was previously discussed.

What is lacking is an anesthetic of instant claims.

Osborne suggests the use of an anesthetic in gel-forming compositions based on PLGA. Claims 1, 5, and 8. Randolph teaches that bipivacaine is an anesthetic suitable for formulation in a sustained release composition. Claims 12, 20, and 26.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include an anesthetic, specifically bipivacaine, in the

composition of Brodbeck. Osborne teaches compositions similar to those of Brodbeck, and suggests the use of anesthetics therein. Randolf teaches that bipivacaine is a known anesthetic suitable for sustained release formulations. As such, inclusion of bipivicaine would be following the express suggestions of the art.

Response to Arguments

It is noted that the rejections to which Applicants' arguments apply have not been maintained in view of the amendments to the claims. The arguments have been considered to the extent that they apply to the rejections currently of record, but are not persuasive.

The two arguments that appear to still apply are (1) the argument that the references do not teach "reduced initial burst", and (2) the argument that the references do not teach the efficacy ratios of claims 2-4, and (3) that the particle sizes of claims 64-39 are not suggested by the art.

In response to the argument regarding reduced initial burst, this term is indefinite as discussed above. Nonetheless, Brodbeck's invention is designed to eliminate the problem of initial burst. See cols 3, 4, 8, and 9. Thus, Brodbeck teaches this limitation.

In response to the argument that the references do not teach the efficacy ratios of claims 2-4, the specification notes that the efficacy ratios depend on the construction of the gel. Because Brodbeck constructs a gel identical to that of instant claims (the only difference being the nature of the active agent), Brodbeck implicitly teaches identical efficacy ratios.

In response to the argument that the particle sizes in the claims were not determined based on concern for the needle size with which the gel is to be delivered. In response, Brodbeck teaches particle sizes from 0.1-100 microns, or from 1-25 microns. Col. 21. These sizes read on those of the instant claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618